

H. Endou, et al.
USSN: 09/786,389
Page 2

Remarks

Claims 1 - 4 are pending in the application. No claims have been amended.

Claim Rejections

35 USC §101 and 35 USC §112

Claims 1 - 4 have been rejected under 35 USC 101 and 35 USC 112 for lacking utility, and for not being supported by a substantial utility, respectively. The rejection is respectfully traversed.

The claimed invention only needs to have one utility and the utility of the instant invention is apparent to one of skill in the art, e.g., transport of amino acids into cells and for medical research into the causes of diseases related to amino acid transport (page 6). The specification discloses utility for the invention in that:

“identification of an amino acid transporter which is specifically expressed in abnormal cells directly participating in the symptoms such as cancer cells (tumor cells) and plays a role of supplying amino acids to the abnormal cells has a very important significance in the clarification of existence and proliferation of such symptom-related cells and also in the development of therapeutic methods for cancer (page 6).”

The utility of the instant invention is known in the art. The claims of the invention are directed to nucleic acids encoding a protein which is an amino acid transporter. The Examiner maintains the rejection of the prior office action, and alleges that the specification “does not provide the nexus between the claimed transporter and diseases or treatments”(page 2, Office Action).

The art teaches specific association between expression of LAT1 and cancer, and such references referred to have been submitted herewith in an IDS. Exemplary references include Kim et al. (Biochim. Biophys. Acta 1565: 112-122.2002), which characterizes the system L-mediated amino acid transporter (LAT1) in T24 human bladder carcinoma cells. Another

H. Endou, et al.
USSN: 09/786,389
Page 3

reference, Tamaj et al. (Cancer Det and Prev, 25(5): 439-445. 2001), describes the expression of LAT1 in a rat model of liver metastasis as having a positive correlation with tumor size.

These references provide ample evidence that LAT1 is associated with the malignant phenotype, and that leucine is incorporated into cancer cells by LAT1. Such evidence provides a clear nexus between the claimed LAT1 transporter and the treatment of cancer. Thus, the claimed invention has a substantial utility and one of skill in the art having the benefit of the disclosure would know how to make and use the claimed invention. As stated previously, the claimed invention only needs to have one utility and here, the utility of the instant invention is apparent to one of skill in the art. Accordingly, Applicants request withdrawal of the rejection and allowance of the claims.

35 USC 112, first paragraph

Claims 1 - 4 have been rejected under 35 USC 112, first paragraph, as failing to comply with the written description requirement. The Examiner alleges that the claims 1 - 4 contain new matter. Applicants respectfully traverse the rejection.

The Examiner alleges that the recitation of "substances similar thereto" in claims 1 and 2 is new matter. Applicants point the Examiner to claim 2 as originally filed, which recites "substances similar thereto." Thus, "substances similar thereto" is not new matter.

The Examiner alleges that the recitation of "wherein 1 to 40 amino acids are substituted, deleted or added" in claim 1 is new matter. Applicants point the Examiner to page 32 of the specification, which discloses the number of amino acids to be altered as "1 to 40 amino acid(s) (see paragraph 2)." Further, on page 32 the specification teaches a partial modification of the protein of the invention can be a deletion, substitution, insertion or addition.

The Examiner alleges that the recitation of "amino acid sequence selected from one or more of" in claim 1 is new matter because the specification does not disclose multiple sequence cell surface protein of SEQ ID NO: 2 and 4. There is ample disclosure throughout the specification for SEQ ID NO: 2 and 4. The Applicants point the Examiner, for example, to page 21 of the specification, which recites "a polypeptide containing a partial amino acid sequence in the amino acid sequence mentioned in SEQ ID NO: 2 or NO: 4."

H. Endou, et al.
USPN: 09/786,389
Page 4

Clearly, claims 1 - 4 do not contain new matter. Accordingly, Applicants request withdrawal of the rejection and allowance of the claims.

35 USC §102

Claims 1 - 4 have been rejected under 102(b) as being anticipated by Gaugitsch (JBC, 1992). Applicants respectfully traverse the rejection.

The Examiner alleges that the Gaugitsch et al. reference discloses a protein which has 100% amino acid sequence identity with the claimed SEQ ID NO: 2. The Examiner further contends that the protein inherently has the function of the transporter.

The Gaugitsch et al. reference does not disclose the entire amino acid sequence of LAT1, rather, the Gaugitsch et al. reference discloses a protein that has 271 amino acid residues. The claims are not anticipated by the Gaugitsch et al. reference because the Gaugitsch et al. reference does not teach or suggest the entire sequences of SEQ ID NOs: 2 or 4. Instead, the reference only discloses a small portion of SEQ ID NOs: 2 and 4 with undetermined activity. Contrary to the Examiner's assertion, there is no teaching in the Gaugitsch et al. reference that leads to the conclusion that the fragment of protein taught would have the same activity as the protein encoded by the claimed nucleic acids.

The instant invention provides, in part, an amino acid transporter protein, LAT1, or part thereof, and DNA coding for the protein or part thereof. The disclosure provides specific examples of the function of LAT1. There are numerous examples in the disclosure that teach specific expression and activity of LAT1, including expression of LAT1 in normal tissue and tumorigenic cells and the biological activity and substrate specificity of LAT1 (see Example 3 and Example 9). The Examples, for example, teach a role for LAT1 in controlling cell proliferation. None of these attributes are disclosed or suggested by the Gaugitsch et al. reference. Accordingly, Applicants request withdrawal of the rejection and allowance of the claims.

Early consideration of the application and claims is earnestly solicited.

H. Endou, et al.
USSN: 09/786,389
Page 5

A request for an extension of time is enclosed, and although it is not believed that no additional fees are needed to consider this submission, the Examiner is hereby authorized to charge our deposit account no. 04-1105 should any fee be deemed necessary.

Respectfully submitted,



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